## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ITW

In re Application of: Yann Echelard et al..

o 7 2005 Serial No.:

10/619,055

Group No.:

1632

Alled:

July 14, 2003

Examiner:

Unknown

For:

METHOD FOR THE RAPID SELECTION OF HOMOZYGOS PRIMARY

CELL LINES FOR THE PRODUCTION OF TRANSGENIC ANIMALS

BY SOMATIC CELL NUICLEAR TRANSFER

Attorney Docket Number:

**GTC-208** 

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN THREE MONTHS OF FILING APPLICATION OR BEFORE MAILING OF A FIRST OFFICE ACTION ON THE MERITS (37 CFR 1.97(b))

## 1. Authority

Pursuant to 37 CFR § § 1.56 and 1.97-1.99, the Applicant cites to the Examiner documents containing information which, in good-faith judgment of the Applicant, may be relevant to the subject matter claimed in the above-identified application. The Applicant also encloses copies of the English-language cited documents.

In submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, or the extent of any search performed, or that more relevant information does not exist.

In submitting this Information Disclosure Statement, the Applicant makes no representation that any document cited in this Information Disclosure Statement is, or is considered to be prior art as defined by 35 USC § \$ 102 and 103.

## 2. Time of Transmittal of Accompanying Information Disclosure Statement

The Information Disclosure Statement transmitted herewith is being filed after three

CERTIFICATE OF MAILING (37 CFR 1.8a)	
I hereby certify that on Harh 2,205 this correspondence is being deposited with the United States Postal	
Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents,	
P.O. Box 1450, Alexandria, VA 22313-1450.	
Dawn C. Greenaway	

months of the filing date of this national application but *before* the mailing date of the first Office action on the merits.

It is Applicant's understanding that no fee is due; however, if the Applicant is incorrect, please charge any necessary fees for the above-captioned application to Deposit Account No. 502092.

The Applicant respectfully requests that:

- a. The Examiner consider the cited information in reaching a determination concerning the patentability of the pending claims; and
- b. The enclosed Form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

The person making this statement is the attorney who signs below on the basis of the information in the attorney's file.

Respectfully submitted,

nted: 0 2 00

By:

Byron V Olsen, Reg. No. 42,960

Attorney for Applicants

175 Crossing Blvd., Suite 410

Framingham, MA 01702

Tel. #(508) 370-5150 Fax #(508) 370-3797

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

MAR 0 7 2005

INFORMATION DISCLOSURE

6

(use as many sheets as necessary)

Sheet 1 of

Substitute for form 1449A/PTO

Comple	ete if Known	
Application Number	10/619,055	
Filing Date	July 14, 2003	
First Named Inventor	Yann Echelard	
Art Unit	1632	
Examiner Name		
Attorney Docket Number	GTC-208	,

		U.S. PA	TENT DOCUMENTS		
Examiner Initials	Cite No.1	Document Number  Number - Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
	<u> </u>	US-			
		US-			
,		US-			
		US-			
····		US-			
		US-			
		US-			

		FOREIG	N PATENT DOCUM	ENTS		
		Foreign Patent Document			Pages, Columns, Lines, Where	
Examiner Initials*	Cite No. <sup>1</sup>	Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date  MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		T
· · · · · · · · · · · · · · · · · · ·						L
<del></del>			ļ			_
	<u> </u>			<del>_</del>		_
	ļ·			· <del>-  </del> · · · · · · · · · · · · · · · · · ·	-	-
Examiner			Date			<u> </u>
Signature			Consider	red		

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov. or MPEP 901/04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

6Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

				Complete if Known		
Substitute fo	or form 1449A/	PTO		Application Number	10/619,055	
INFOR	MATION	DISC	LOSURE	Filing Date	July 14, 2003	
				First Named Inventor	Yann Echelard	
STATEMENT BY APPLICANT  (use as many sheets as necessary)				Group Art Unit	1632	
(use	as many sneets	as necessa	<i></i>	Examiner Name		
Sheet	2	of	6	Attorney Docket Number	GTC-208	

	O	THER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	_
Examiner Initials *	Cite No. <sup>1</sup> 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
		Alberio R, et al., Mammalian Oocyte Activation: Lessons from the Sperm and Implications for Nuclear Transfer, INT J DEV BIOL 2001; 45: 797-809.	
		Arroyo, A. et al., In Vivo Roles Of Integrins During Leukocyte Development And Traffic: Insights From The Analysis Of Mice Chimeric For $\alpha_5$ , $\alpha_V$ , and $\alpha_4$ Integrins. THE JI 2000;165: 4667-4675.	
		Baguisi A, et al., Production of Goats by Somatic Cell Nuclear Transfer, NAT BIOTECH 1999; 17: 4 56-461.	
		Bondioli K, et al., Production of Identical Bovine Offspring by Nuclear Transfer, THERIOGENOLOGY 1990; 33: 165-174.	
		Byrd, N, et al., Hedgehog Is Required For Murine Yolk Sac Angiogenesis.  DEVELOPMENT 2002; 129: 361-372.	
		Cibelli JB, et al., Cloned Transgenic Calves Produced From Nonquiescent Fetal Fibroblasts. SCIENCE 1998; 280: 1256-1258.	
		Gavin, W.G., Gene Transfer Into Goat Embryos, TRANSGENIC ANIMALS – GENERATION AND USE, L. M. Houdebine ed., (Harwood Academic Publishers Gmbh., 1996).	
		Helgason, C et al., Targeted Disruption Of SHIP Leads To Hemopoietic Perturbations, Lung Pathology, And A Shortened Life Span. GENES & DEV. 1998; 12: 1610-1620.	

Examiner	Date
Signature	Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at www.uspto.gov. or MPEP 901/04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for	or form 1449A/	PTO		Comple	ete if Known
INIEOD		DICCI	OSLIDE	Application Number	10/619,055
	MATION MENT B			Filing Date	July 14, 2003
				First Named Inventor	Yann Echelard
(use	as many sheets	s as necesso	ıry)	Art Unit	1632
				Examiner Name	
Sheet	3	of	6	Attorney Docket Number	GTC-208
	1	ı	i	•	'

Hu, JF, et al., Genomic Deletion Of An Imprint Maintenance Element Abolishes Imprinting Of Both Insulin-Like Growth Factor II And H19. J. BIOL. CHEM. 1997; 272: 20715-20720.
Hwang, HY, et al., Creation Of Homozygous Mutants Of Leishmania Donovani With Single Targeting Constructs. J. BIOL. CHEM. 1996; 271: 30840-30846.
Jain, M, et al., Targeted Inactivation Of GαI Does Not Alter Cardiac Function Or β-Adrenergic Sensitivity. Am. J. PHYSIOL. 2001; 280: 569H-575.
Kasinathan P, et al., Effect of Fibroblast Donor Cell Age and Cell Cycle on Development of Bovine Nuclear Transfer Embryos In Vitro, BIOL REPROD. 2001; 64(5): 1487-1493.
Kasinathan P, et al., Production of Calves from G1 Fibroblasts, NATURE BIOTECH 2001; 19: 1176-1178.
Klug, M, et al., Genetically Selected Cardiomyocytes From Differentiating Embryonic Stem Cells Form Stable Intracardiac Grafts. J. CLIN. INVEST. 1996; 98: 216-224.
Koike, H, et al., Efficient Biallelic Mutagenesis With Cre/Loxp-Mediated Inter- Chromosomal Recombination. EMBO REPORTS 2002; 3: 433-437.
Kundu, R et al., Targeted Inactivation Of The Coagulation Factor IX Gene Causes Hemophilia B In Mice. BLOOD 1998; 92: 168-174.
Lai, L, et al., Feasibility of Producing Porcine Nuclear Transfer Embryos by Using G2/M Stage Fetal Fibroblasts as Donors, BIOL REPROD 2001; 65: 1558-1564.

Examiner	Date
Signature	Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov. or MPEP 901/04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute fo	or form 144	9A/PTO		Complete if Known			
INFOR	NA A TOTA	NI DICC	LOCUDE	Application Number	10/619,055		
			LOSURE	Filing Date	July 14, 2003		
				First Named Inventor	Yann Echelard		
(use	e as many sh	neets as necess	sary)	Art Unit	1632		
	_			Examiner Name			
Sheet	4	of	6	Attorney Docket Number	GTC-208		
	•	•	•	,	•		

Lebel, M, et al., A Deletion Within The Murine Werner Syndrome Helicase Induces Sensitivity To Inhibitors Of Topoisomerase And Loss Of Cellular Proliferative Capacity. PROC. NATL. ACAD. SCI. U.S.A. 1998; 95: 13097-13102.
Lim, S, et al., A Shortened Life Span Of EKLF-/- Adult Erythrocytes, Due To A Deficiency Of Beta -Globin Chains, Is Ameliorated By Human Gamma -Globin Chains. BLOOD 1997; 90: 1291-1299.
Meng L, et al., Rhesus Monkeys Produced by Nuclear Transfer, BIOL REPROD 1997; 57: 454-459.
Mortensen, R, et al., Production Of Homozygous Mutant ES Cells With A Single Targeting Construct. MOL.CELL. BIOL. 1992; 12, 2391-2395.
Nagy, A, et al., Targeted Mutagenesis: Analysis Of Phenotype Without Germ Line Transmission. J. CLIN. INVEST. 1996; 97: 1360-1365.
Qu, CK, et al., Biased Suppression Of Hematopoiesis And Multiple Developmental Defects In Chimeric Mice Containing Shp-2 Mutant Cells. Mol. CELL. BIOL. 1998; 18: 6075-6082.
Sakai, E, et al., Recombination And Transcription Of The Endogenous Ig Heavy Chain Locus Is Effected By The Ig Heavy Chain Intronic Enhancer Core Region In The Absence Of The Matrix Attachment Regions. PROC. NATL. ACAD. SCI. U. S. A. 1999; 96: 1526-1531.
Saleque, S, et al., The Zinc-Finger Proto-Oncogene Gfi-1b Is Essential For Development Of The Erythroid And Megakaryocytic Lineages. GENES & DEV. 2002; 16: 301-306.

Examiner	Date
Signature	Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov. or MPEP 901/04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

INFORMATION DISCLOSURE				Complete if Known		
			COUDE	Application Number	10/619,055	
				Filing Date	July 14, 2003	
	(use as many sheets as necessary)			First Named Inventor	Yann Echelard	
(use				Art Unit	1632	
				Examiner Name		
Sheet	5	of	6	Attorney Docket Number	GTC-208	
	1	'	•	1	•	ノ

Soudais, C, et al., Targeted Mutagenesis Of The Transcription Factor GATA-4 Gene In Mouse Embryonic Stem Cells Disrupts Visceral Endoderm Differentiation In Vitro. DEVELOPMENT 1995; 121: 3877-3888.
Sowell, M et al., Targeted Inactivation Of Alpha I2 Or Alpha I3 Disrupts Activation Of The Cardiac Muscarinic K+ Channel, IK+Ach, In Intact Cells, PROC. NATL. ACAD. SCI. U.S.A. 1997; 94: 7921-7926.
Stanford, W, et al., Expression Trapping: Identification Of Novel Genes Expressed In Hematopoietic And Endothelial Lineages By Gene Trapping In ES Cells, BLOOD 1998; 92: 4622-4631.
Wall RJ, et al., Transgenic Dairy Cattle: Genetic Engineering on a Large Scale, J DAIRY SCI. 1997; 80(9): 2213-24.
Wilmut I, et al., Viable Offspring Derived From Fetal and Adult Mammalian Cells, NATURE 1997; 385: 810-813.
Wells DN, et al., Production of Cloned Calves Following Nuclear Transfer with Cultured Adult Mural Granulosa Cells, BIOL REPROD 1999; 60: 996-1005.
Wells, et al., Cloning livestock: a return to embryonic stem cells. Trends in Biotechnology. Vol. not known, no. not known, Month, not known, 1-4.
Weiss, M and Orkin, S, In Vitro Differentiation Of Murine Embryonic Stem Cells New Approaches To Old Problems. J. CLIN. INVEST. 1996; 97: 591-595.
Wu, Q, et al., Generation And Characterization Of Mice Deficient In Hepsin, A Hepatic Transmembrane Serine Protease. J. CLIN. INVEST. 1998; 101: 321-326.

Examiner	Date
Signature	Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov. or MPEP 901/04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

INFORMATION DISCLOSURE				Complete if Known		
			COLUDE	Application Number	10/619,055	
				Filing Date	July 14, 2003	
(use as many sheets as necessary)		First Named Inventor	Yann Echelard			
		Art Unit	1632			
	_			Examiner Name		
Sheet	6	of	6	Attorney Docket Number	GTC-208	
	1	ı	•	•	•	

Yang X, et al., Nuclear Totipotency of Cultured Rabbit Morulae to Support Full- Term Development Following Nuclear Transfer, BIOL REPROD 1992; 47: 636-643.
Yong Z and L Yuqiang, Nuclear-Cytoplasmic Interaction and Development of Goat Embryos Reconstructed by Nuclear Transplantation: Production of Goats by Serially Cloning Embryos, BIOL REPROD. 1998; 58: 266-269.
Zou X, et al., Generation Of Cloned Goats (Capra Hircus) From Transfected Foetal Fibroblast Cells, The Effect Of Donor Cell Cycle, MOL REPROD DEV. 2002; 61: 164-172.

Examiner	Date
Signature	Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov. or MPEP 901/04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.